A Study Protocol for Tracking Quality of Life Among U.S. Service Members Wounded in Iraq and Afghanistan: The Wounded Warrior Recovery Project

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A Study Protocol for Tracking Quality of Life Among U.S. Service Members Wounded in Iraq and Afghanistan: The Wounded Warrior Recovery Project

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ABSTRACT There is a need for more work to understand the quality of life (QOL) outcomes of survivors of Operations Enduring Freedom and Iraqi Freedom combat injury to improve care and treatment, and prevent poor physical, psychological, and social outcomes. We describe the study design and methods of the Wounded Warrior Recovery Project, a study supported by the Department of Defense that will track close to 10,000 military personnel wounded in Operations Enduring Freedom and Iraqi Freedom. The overall objective of the 6-year longitudinal study is to track changes in QOL and describe variations in those changes as they relate to sociodemographic factors, injury characteristics, service-related factors, clinical/diagnostic measures including traumatic brain injury and posttraumatic stress disorder, and medical procedures and services. The Wounded Warrior Recovery Project study will be among the first longitudinal population-based investigations of QOL outcomes after combat injury and will provide a basis upon which large-scale epidemiological studies can be conducted.

INTRODUCTION

The survival rate of those injured in combat in Operations Enduring Freedom and Iraqi Freedom (OEF/OIF) is the highest in modern history primarily because of advanced protective gear and rapid effective medical care.[1–4] To date, approximately 50,000 military personnel have been combat injured in these conflicts, with 16,000 of them so severely wounded that they likely would not have survived in previous conflicts.[2,5] Both the causes and outcomes of these combat injuries are historically distinctive, with improvised explosive devices resulting in a high risk of mild and more severe traumatic brain injury (TBI). In addition to physical trauma, mental health outcomes such as post-traumatic stress disorder (PTSD) and depression have also received widespread attention, because of their relatively high prevalence among OEF/OIF veterans.[6]

Quality of Life Perspective

Although the financial cost of compensating and caring for the wounded will be staggering (upwards of $700 billion according to some),[7] the monetary cost will likely be dwarfed by the personal, often unmeasured impact. Because people are living longer in general (often with chronic conditions) and because trauma victims have higher survival rates than ever, health care practitioners and researchers have found objective disease and disability status alone is insufficient for capturing the impact of illness/injury.[8] Quality of life (QOL) is a concept that, when measured well, is thought to shed light on both the objective and the subjective experience of the individual. QOL includes physical health and functioning as well as self-perceptions of social functioning, mental health, and general well-being.[9] QOL and health-related QOL in particular are increasingly being used as outcomes for chronic-disease patients and trauma sufferers because of their importance in providing subjective self-assessments of health status, in addition to objective clinical information. QOL measures provide additional information that encompasses the broader picture of the individual's life circumstances,[8] and this information may be useful to assess the need for care and rehabilitation.[10,11]

A theoretical model of trauma and its effect on QOL, developed by Sprangers and Schwartz[12] and modified for our purposes, is useful for conceptualizing trauma-induced QOL and how people's perception of it may change over time. As shown in Figure 1, the trauma is the catalyst that brings about change in the individual's health status. Antecedents refer to both stable dispositional traits and trauma-specific characteristics. These antecedents, such as sociodemographic characteristics, personality, and injury severity, are thought to influence the mechanisms of appraising the event. Mechanisms to accommodate the trauma could refer to behavioral, cognitive, and affective processes to accommodate the trauma (e.g., coping style and social support), as well as actual treatments and interventions. The definition of response shift is a change in the meaning of one's self-evaluation of QOL as a result of changes in internal standards, values, or reconceptualization of QOL. Antecedents are thought to directly and indirectly affect response shift, and a dynamic feedback loop describes how perceptions of QOL can stabilize despite a traumatic injury. Although highly psychological and perhaps untestable in its entirety, this model is useful for thinking about how some

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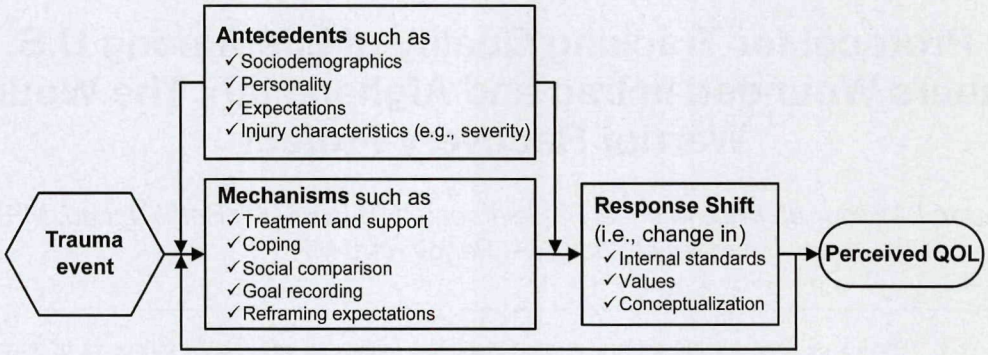

FIGURE 1. Theoretical model of QOL based on Sprangers and Schwartz.[12]

individuals successfully cope with trauma and experience high levels of QOL.

QOL studies have been conducted with civilian who are not patients, as part of social indicator surveillance,[13,14] and with a wide range of clinical samples, including those with cancer, migraine, asthma, HIV, cardiovascular disease, chronic pain, and trauma.[15–21] QOL has also been assessed in combat-injured military personnel to some degree,[6,11] but these studies have often been cross-sectional, relied on convenience samples, or focused on a specific type of trauma such as limb loss or concussion. In its report to the Secretary of Defense, the Institute of Medicine called for comprehensive, long-term studies that address the unique challenges and readjustment issues faced by those deployed to OEF/OIF.[3] The Institute of Medicine encouraged research that would minimize methodological limitations related to sampling, measurement, design, and breadth of variables to move the field forward with regard to understanding the physical, psychological, and social impact of combat. Although there are well-designed, large, prospective cohort studies of "overall" military personnel, such as the Millennium Cohort Study,[22] there is a need for more work specifically targeting the QOL outcomes of "survivors" of OEF/OIF combat injury to improve care and treatment, and prevent poor physical, psychological, and social outcomes.

PURPOSE

The purpose of this article is to describe a Department of Defense (DoD) effort that is initially attempting to track close to 10,000 military personnel wounded in OEF/OIF since 2010, and assess their short- and long-term QOL. The study, called the Wounded Warrior Recovery Project (WWRP), is enrolling both discharged and active duty personnel. We describe the objectives and methods of the WWRP study, and discuss its potential for providing a basis upon which additional epidemiological studies can be conducted.

STUDY DESIGN

WWRP is currently planned as a 6-year longitudinal study of an initial cohort of about 10,000 battle-injured personnel identified in the Expeditionary Medical Encounter Database (EMED), formerly known as the Navy–Marine Corps Combat Trauma Registry.[23] The EMED, developed by the Naval Health Research Center (NHRC), is a deployment health database consisting of documented clinical encounters of each service member injured while deployed in support of OEF/OIF. Web-based surveys supplemented by mailed and telephone surveys are planned every 6 months (total of 13 surveys) so that relatively short- and long-term QOL and its correlates can be assessed. Supplemental data from existing DoD personnel and medical data sets and point-of-injury data from the EMED will ensure the most current contact information for participants over time and provide a broad range of correlates with which to link to QOL. Investigators obtained institutional review board approval for the study from NHRC and received a Certificate of Confidentiality from the National Institutes of Health, National Institute of Mental Health to afford additional participant protections. Approvals or support have also been obtained from the Defense Manpower Data Center, the Office of the Assistant Secretary of Defense for Health Affairs, the DoD Washington Headquarters Services, and the Office of Management and Budget (pending). A notice announcing the project and soliciting comments was published in the Federal Register in 2010 (75 FR 81242).

The overall objective of the WWRP study is to track changes in QOL and describe variations in those changes as they relate to sociodemographic factors, injury characteristics, service-related factors, clinical/diagnostic measures including TBI and PTSD, and medical procedures and services. By linking various data sources, a wide range of both cross-sectional and longitudinal research questions will be examined, including the following:

(1) What is the trajectory of QOL among injured service members, and how does it compare with trajectories among civilian severity- and age-matched trauma patients?
(2) What are the correlates of changes in QOL over time, in particular, baseline PTSD and TBI?
(3) Do participant-reported changes in PTSD co-occur with changes in QOL?
(4) What is the course of QOL among those with rare battle injuries?

(5) Does depression mediate the relationship between injury severity and QOL?
(6) To what extent do cross-sectional and longitudinal predictors of QOL differ, and what are the implications for service provision?
(7) What injury factors and treatments documented near the point of injury predict subsequent QOL?
(8) Are there optimal types and timing of procedures and services for specific injuries that positively influence QOL?
(9) Which military injury subgroups benefit most from resources allocated toward improving QOL?
(10) Is QOL a useful fundamental metric for assessing treatment/rehabilitation effectiveness within the DoD and Department of Veterans Affairs?

Sampling Strategy

The study cohort is defined as those individuals in the EMED registry who survived a combat-related injury after December 2009. This date of inclusion was chosen because in January 2010, the EMED became a tri-service capability. Two other criteria for inclusion in WWRP are an assigned Injury Severity Score (ISS; a widely used medical questionnaire to assess trauma severity)[24,25] and the recording of personal identifying information for linking to other existing databases.

Recruitment will take place over a 1 to 2 year period. Pilot testing of procedures has been conducted and enrollment began in spring 2013. As shown in Figure 2, a total of 9,635 unique service members have been identified in the EMED and confirmed with military death records to be still living (these numbers closely agree with those published by the Defense Casualty Analysis System).[26] DoD data repositories, including the Military Health System Data Repository and the Defense Enrollment Eligibility Reporting System (DEERS), are used to determine potential participants' active duty and deployment status, as well as e-mail addresses, work and/or home postal mailing addresses, and work and/or home telephone numbers. These databases indicate that 71% of the EMED cases are active duty, whereas 29% are separated or in the reserves. Of those on active duty, 15% can be expected to be deployed at a given time. Active duty, separated/reserve, deployed, and nondeployed individuals are invited to participate. Using a stepped approach, nondeployed active duty personnel are being recruited first. Deployed service members will be recruited upon their return stateside because access to e-mail and address information is thought to be more reliable. These same databases will be used to provide quarterly updates of cohort members' change in active duty and deployment status, as well as changes in e-mail and other contact information. One other relatively small contribution to the cohort (n = 1,200) will be those who are newly injured after spring 2013 (about 100 per month). Because of issues associated with predicting combat casualties, 100 per month is an estimate based on the casualty rate as of summer 2013.

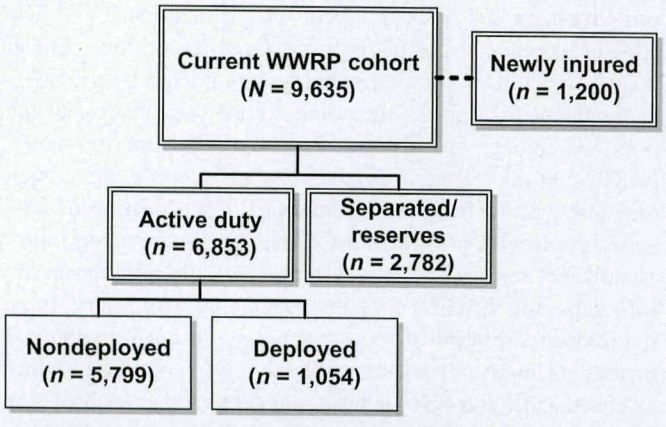

FIGURE 2. WWRP cohort drawn from the Expeditionary Medical Encounter Database.

Enrollment Procedures

Successful recruitment of participants is critical in establishing a large and representative cohort. Survey methodologists advocate for some type of introductory approach to potential participants, and postcards have been shown to be a relatively straightforward and low-cost procedure.[27,28] An eye-catching postcard (shown in Fig. 3) is being mailed to potential participants at their primary address (as recorded in their DEERS personnel record). The postcard announces the study, and lets the potential participant know that he or she will be contacted soon.

Up to seven attempts are made to recruit potential participants. About 2 weeks after the postcard is sent, participants receive an e-mail inviting them to click on a link to the secure study website where they can obtain further information about the study (see Fig. 4 for a screenshot of the WWRP website). This e-mail also contains a preassigned unique identification number and password that allows the participant to log into the study website. The e-mail provides a brief introduction to the study as well as information on how to opt out. Once logged in for the first time, potential participants read the informed consent form and, should they wish to participate, click a checkbox stating that they agree to participate in the study. They are then able to update their e-mail address and proceed to taking the first survey. Potential participants who do not log on to the study website to consent yet or who do not opt out are sent another invitational e-mail about 2 weeks later. Those still not responding are mailed an introductory letter containing similar language approximately 2 weeks after the second e-mail. If this is unsuccessful, another letter is mailed 1 month after the first letter. If the participant still has not responded, a maximum of three further attempts at contact are made (e-mail, letter, or telephone as appropriate) to ensure that the participant is aware of the study and has been given an opportunity to participate. If at any time a participant asks to opt out of the study, enrollment attempts immediately stop.

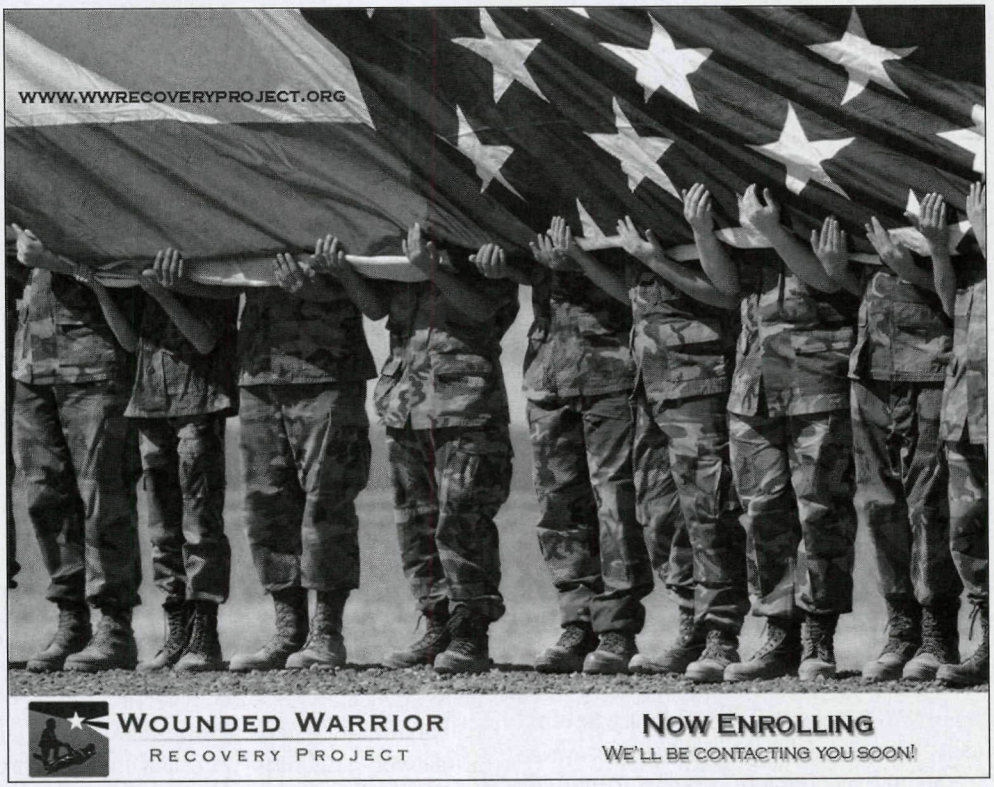

FIGURE 3. Introductory postcard mailed to potential participants.

Periodicity of Surveys

Participants in the WWRP are offered the surveys online, over the phone, or by mail, although it is anticipated that because of the cohort's relatively young age and familiarity with the Internet, as well as the convenience factor, the majority of participants will choose to complete the surveys online.[11] Each survey has a window for completion that is tied to the signing of the consent form. After consenting, the participant has a 4- to 5-week window in which to complete the baseline survey, after which the online portal closes. Six months after consent, the portal will reopen for the 6-month follow-up survey and remain open for 4 weeks. Twelve months after consent the portal will reopen for the 12-month survey and remain open for 4 weeks. This process will repeat for all 13 surveys.

Survey Reminders and Cohort Maintenance

An automated data collection and tracking system has been designed to maximize retention while minimizing staff time spent following participants and gathering and entering data. Because the system is automated, once a participant is enrolled, the remainder of his or her 6-year participation is completed automatically. The participants perform data entry, which minimizes staff time as well as errors. The online system will open the survey portal as appropriate, inform the participant via e-mail when it is time to complete a survey, and remind the participant of incomplete surveys (up to three reminders). If a participant nears the end of his or her 4-week window and the current survey remains incomplete, study staff may send a reminder letter or attempt up to 10 reminder phone calls. If a participant misses a survey entirely, he or she will be contacted to complete the next survey. For each survey completed, participants are e-mailed a $20 gift code to an online retailer.

Sources of Data and Measures

EMED Variables

As described in the Sampling Strategy section, the EMED defines the cohort of battle-injured military personnel to be enrolled and followed. The EMED has already proved to be a valuable data repository, having served as the basis for numerous investigations of deployment-related medicine.[24–46] The EMED contains information abstracted from the clinical records of military personnel that are completed by providers at treatment facilities in the combat zone (i.e., nearest to the point of injury) and throughout the continuum of care.[23] NHRC-certified nurse coders review all records and assign diagnostic codes from the International Classification of Diseases, 9th Revision, Clinical Modification, Abbreviated Injury Scale 2005, and ISS coding systems.[24,47,48] In addition to the ISS data, the EMED contains mechanism of injury (e.g., improvised explosive device, blast, or gunshot); anatomical location of injury; disposition of patient (e.g., returned to duty or evacuated); and date of birth, age, sex, and branch of service. Date of injury is additionally recorded and is an important variable for computing time since injury.

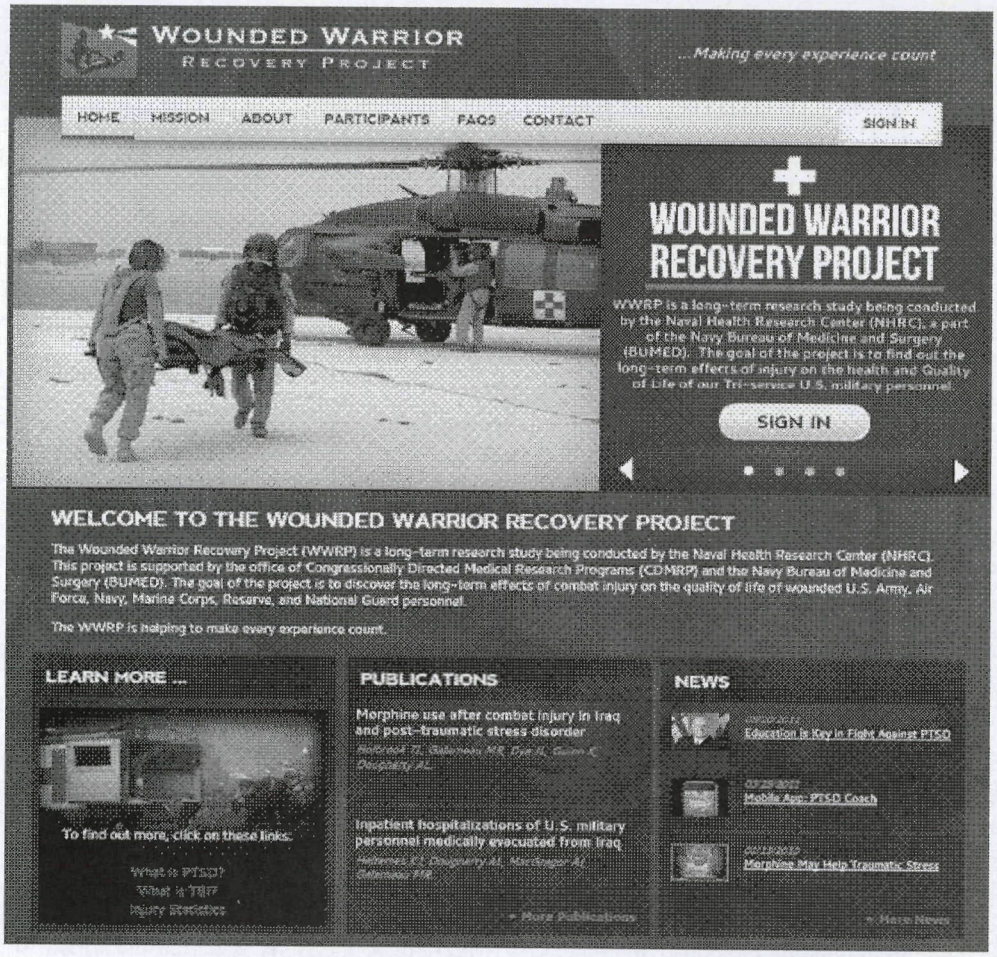

FIGURE 4. A screenshot of the WWRP website.

Quality of Life and Other Self-Report Survey Measures

The initial survey will consist of four instruments comprising 132 items. Follow-up surveys will consist of three instruments, composed of 116 items. QOL will be measured using the Quality of Well-Being Scale—Self-Administered that assesses the domains of mobility, physical functioning, and social activity.[49,50] Self-reported symptoms are assessed by questions that ask about the presence or absence of different chronic and acute symptoms or conditions.[49,50] The questions are combined into a total score that provides a numerical point-in-time expression of well-being (0 = death, 1 = asymptomatic functioning).

To assess depression, the Center for Epidemiological Studies Depression Scale, a widely used and validated self-reported depression scale,[51] will be employed. The Center for Epidemiological Studies Depression Scale consists of 20 questions indicative of depression during the past week.

A PTSD Checklist will be used to measure PTSD symptoms and severity. The PTSD Checklist consists of 17 questions that assess symptoms in the last month in relation to a generic "stressful experience."[52] The scores from the questions are summed up into a total symptom severity score.

To gather circumstantial information surrounding the injury, we will use a 16-item questionnaire based on the validated and published injury event-related factors questionnaire.[53] The questionnaire gathers perceived threat to life, witnessing of injury to others, amount of warning before the event, and perceived control over the event, which have all been shown to be significant predictors of outcomes among civilian trauma sufferers.[53]

Supplemental Data and Analyses

WWRP study staff have access to multiple established DoD databases that will provide important supplemental administrative and medical data. Linking WWRP participants' self-reported survey data (QOL, depression, PTSD symptoms) and information about the initial injury and diagnoses from EMED with these other data sources will allow more comprehensive examination of QOL risk factors, mediators/moderators of QOL change, treatments, and comorbid conditions. Table I presents information about several supplemental data sets and examples of additional variables that will be provided.

Cross-sectional and longitudinal data analyses, such as those conducted for the exemplar research questions listed

TABLE I. Supplemental Sources of Administrative, Medical, and Trauma Event Data

Database	Information Provided
DEERS	DEERS is used to determine active duty status, participant demographic information, length and number of deployments, and military career information (e.g., rank).
CTS	CTS is used to determine deployment information including location of deployments and military occupation.
SIDR	The SIDR database provides information for all military hospitalizations, including diagnoses, ICD-9 medical procedure codes, number of days hospitalized, and medical care costs.
SADR	The SADR database provides information for all military outpatient visits, including diagnoses, number of visits, and Current Procedural Terminology codes that identify medical services and procedures.
PDHA/PDHRA	The PDHA/PDHRA database contains physical and behavioral health measures from all service members within a month of returning from deployment, and again 90–180 days later. Measures include self-rated health, suicide risk, tobacco and alcohol consumption, and health symptoms.
PDTS	PDTS is a centralized data repository that tracks patients' medication profile for all DoD beneficiaries regardless of the point of service.
NHIS	Using specialty software, the QWB-SA QOL scores will be computed for an age-matched sample of civilians from the NHIS national database for comparison with the WWRP cohort.
CHAMPS	CHAMPS, maintained at NHRC, provides career and personnel related variables (e.g., demotions, promotions) that may be associated with QOL.
Classified/Unclassified Tactical and Operational Databases	These data sources provide characteristics of the event that generated the injury (e.g., personal protective gear worn, number of others killed or injured in event).

CTS, Contingency Tracking System; SIDR, Standard Inpatient Data Record; ICD-9, International Classification of Diseases, 9th Revision, Clinical Modification; SADR, Standard Ambulatory Data Record; PDHA/PDHRA, Post-Deployment Health Assessment/Reassessment Program; PDTS, Pharmacy Data Transaction Service; NHIS, National Health Interview Survey; QWB-SA, Quality of Well-Being Scale Self-Administered; CHAMPS, Career History Archival Medical and Personnel System.

above, will primarily consist of multivariate procedures such as multiple linear regression and logistic regression. When appropriate, time since injury and injury severity will be controlled for to assess the independent contribution of other factors (e.g., postinjury PTSD diagnosis) on QOL and QOL changes. Assessment and modeling of missing data will be an important ongoing analysis; multiple imputation methods will be considered, if appropriate, to reduce the nonresponse bias.[54,55]

Demographic Characteristics of the Participants

Table II presents several demographic and background characteristics of active duty, separated, and reserve status personnel combined who are currently in the EMED and who are being invited to participate (n = 9,635). On average, the cohort is young at the time of their initial injury (aged 26 years), and the majority are male. Soldiers and Marines make up 97% of the cohort. Eighty-three percent of the cohort are white, and 95% are enlisted personnel. About 20% of the cohort had an initial serious/severe battle injury, while 80% had injuries that fell within the minor to moderate severity range.

POTENTIAL VALUE OF THE STUDY

Identification and treatment of risk factors for poor long-term QOL outcomes have become integral components of modern combat casualty care.[11,56,57] However, QOL studies to date have largely been short term, included a limited number of variables, or focused on a single and severe injury type. The WWRP study will be among the first longitudinal population-based investigations of QOL outcomes after combat injury. Strengths of the study include a wide range of types and severity of injuries; a large cohort so that even rare injuries can be investigated; inclusion of medical and contextual information collected near the point of injury; and the capacity to link to additional military, medical, and administrative data sources. Although the initial thrust is for a cohort of almost 10,000, efforts are under way to assess the feasibility of capturing all casualties (upwards of 50,000). An additional strength of the study is the ability to add survey instruments

TABLE II. Cohort Demographic and Service Characteristics (n = 9,635)

Characteristic	% or Mean (SD)
Age, Years	26 (5.74)
Sex	
Male	98
Female	2
Branch of Service	
Army	70
Marine Corps	26
Navy	2
Air Force	1
Race/Ethnicity	
White/Hispanic	83
Black	7
Asian	3
American Indian	1
Native Hawaiian/Pacific Islander	0.5
Other/Unknown	5
Enlisted/Officer Status	
Enlisted	95
Commissioned and Warrant Officers	5
ISS	5.65 (7.56)
ISS Categories	
Minor to Moderate (1–8)	80
Serious to Severe (>9)	20

as needed to investigate emerging issues of interest in the injured population. WWRP results will likely play an important role in informing military health policy, allocating resources, guiding development of strategic plans, and assessing the effectiveness of treatments for those wounded in combat.

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14. ABSTRACT
There is a need for rnore work to understand the quality of life (QOL) outcomes of survivors of Operations Enduring Freedorn and Iraqi Freedotn combat injury to improve care and treatment, and prevent poor physical, psychological, and social outcomes. We describe the study design and methods of the Wounded Warrior Recovery Project, a study supported by the Department of Defense that will track close to 10,000 military personnel wounded in Operations Enduring Freedom and Iraqi Freedom. The overall objective of the 6-year longitudinal study is to track changes in QOL and describe variations in those changes as they relate to sociodemographic factors, injury characteristics, service-related factors, clinical/diagnostic measures including traumatic brain injury and posttraumatic stress disorder, and medical procedures and services. The Wounded Warrior Recovery Project study will be among the first longitudinal population-based investigations of QOL outcomes after combat injury and will provide a basis upon which large-scale epidemiological studies can be conducted.

15. SUBJECT TERMS
Combat trauma, quality of life, ongitudinal study, Expeditionary Medical Encounter Database (EMED), Wounded Warrior Recovery Project (WWRP)

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